REMARKS/ARGUMENTS

The rejections presented in the Office Action dated March 37, 2006 (hereinafter Office Action) have been considered. Claims 1-62 remain pending in the application. Claims 33 and 45 are indicated as being allowable. Claims 1, 42, 49, and 58 have been amended. No claims have been canceled or added. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

Claims 1-6, 8-9, 11-12, 14-32, 34-44, 46-53, 55 and 58-62 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,205,357 to *Ideker et al.* (hereinafter "*Ideker*").

The subject matter of Applicant's pending claim is directed to a reconfigurable cardiac device that operates in a monitoring mode for monitoring cardiac electrical activity and, if needed or indicated, can be reconfigured for operation as a cardiac stimulation device. Applicant's specification, at page 9, lines 8-13, teaches that:

> A reconfigurable cardiac monitoring/stimulation device may advantageously be used where it is desired to provide cardiac monitoring for diagnosis, before providing cardiac stimulation therapy. For example, a reconfigurable approach of the present invention allows upgrading the device from purely a monitoring and diagnostic system to a therapy delivery system for patients who develop or are diagnosed with conditions necessitating cardiac therapy.

Applicant's specification, at page 21, lines 8-18, further teaches that:

> A reconfigurable cardiac device in accordance with the present invention includes a therapy portion 300, which is disabled when the cardiac device is operated in a first monitoring and recording mode, and enabled when operating in a second monitoring and therapy mode. The therapy portion 300 may be physically switchable, using a hardware switch, to enable/disable the therapy portion 300. The therapy portion may be enabled/disabled via control

signals from the control system 305. It is also contemplated that a combination of hardware and software may be used to enable/disable the therapy portion 300. For example, the header 100 (see for example, Figures 7 and 8) may include a proximity switch or other component required to enable the therapy portion 300. The control system 305 may require detection of one or more therapy electrodes before enabling the therapy portion 300 (*emphasis added*).

Support for the amendments to claims 1, 42, 49, and 58 is found in the excerpts of Applicant's specification reproduced above and elsewhere in Applicant's disclosure.

Each of Applicant's independent claims recites, in various forms, that the subject device can operate in a purely monitoring mode (in which energy delivery circuitry or cardiac stimulation therapy delivery is disabled) and be reconfigured to provide cardiac stimulation therapy.

Ideker discloses an implantable system for detecting and treating a medical condition of the heart. According to *Ideker,* the disclosed device predicts a future onset of a cardiac arrhythmia based on detected electrical activity, and delivers a first cardiac electrical therapy prior to the onset of the cardiac arrhythmia. If the first therapy is not effective, a second cardiac electrical therapy of higher energy is delivered. *See, e.g.,* column 5, lines 12-42.

Ideker does not teach a cardiac device that operates exclusively in a monitoring mode/configuration, such that its cardiac therapy circuitry is disabled. *Ideker* does not teach a cardiac device that transitions or is switchable from a monitoring-only mode/configuration to a stimulation mode/configuration, in which the disabled cardiac therapy circuitry is enabled.

Rather, *Ideker's* device, as described, must have its cardiac therapy circuitry ready for operation so that it can deliver its stimulation therapy to the heart prior to the onset of a

cardiac arrhythmia. *Ideker* wholly fails to contemplate the reconfigurable features of Applicant's claimed subject matter.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102. Applicant respectfully submits that *Ideker* does not teach every element of claims 1-6, 8-9, 11-12, 14-32, 34-44, 46-53, 55 and 58-62, and therefore fails to anticipate these claims.

The disclosure in an anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo Foundation for Medical and Education Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003). See, also, MPEP § 2121.01. Applicant respectfully asserts that *Ideker's* description of cardiac device that monitors cardiac electrical activity and delivers cardiac electrical therapy is insufficient to support the anticipation rejection of Applicant's claims. Applicant respectfully submits that it would not be possible for one skilled in the art to arrive at Applicant's claimed structures and methods using *Ideker's* cardiac device teachings without undue experimentation.

Applicant submits that the reconfigurable features of Applicant's claims are clearly not taught expressly in *Ideker*. Applicant further submits that *Ideker* does not inherently teach the reconfigurable features of Applicant's claims. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the

reference, and that it would be so recognized by persons of ordinary skill. Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). The reconfigurable features of Applicant's claims are not features that are necessarily present in the *Ideker* device.

For at least these reasons, Applicant's claims 1-6, 8-9, 11-12, 14-32, 34-44, 46-53, 55 and 58-62 are not anticipated by *Ideker*.

Claims 7 and 13 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Ideker* in view of U.S. Patent No. 4,312,355 to *Funke.* (hereinafter *"Funke"*). Claims 10, 54, 56, and 57 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Ideker*.

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142. Applicant respectfully traverses the rejection since the prior art combinations fail to disclose all the claim limitations and there would be no motivation to combine the references as proposed by the Examiner.

The combination of *Ideker* and *Funke* fails to teach or suggest the reconfigurable features of Applicant's claims 7, 10, 13, 54, 56, and 57 for reasons discussed above. Moreover, the asserted combination fails to provide the requisite suggestion or motivation to combine reference teachings, as neither *Ideker* nor *Funke* contemplates a cardiac device that operates exclusively in a monitoring mode/configuration, such that its cardiac therapy circuitry is disabled, or a cardiac device that transitions from a monitoring-only mode/configuration to a stimulation mode/configuration. Further, there is no reasonable expectation of success that Applicant's claimed subject matter recited in claims 7, 10, 13, 54, 56, and 57 can be arrived at given the teachings or suggestions of *Ideker* and *Funke*.

For at least these reasons, claims 7 and 13 are patentable over *Ideker* and *Funke*, and claims 10, 54, 56, and 57 are patentable over *Ideker*.

Concerning the amendments made to claims 1, 42, 49, and 58, Applicant asserts that these amendments are not made for purposes of patentability, nor do these amendments narrow the scope of these claims. Rather, the amendments to claims 1, 42, 49, and 58 merely expressly recite aspects of the terms "monitoring mode" or "monitoring configuration" which are inherent in the original claims. The Federal Circuit has stated that an amendment that only make express a recitation of a feature that was already inherent in the original claim is not a narrowing of the scope of the properly construed claim. *TurboCare v. General Electric Co.*, 264 F.3d 1111 (Fed. Cir. 2001); *Bose Corp. v. JBL, Inc.*, 274 F.3d 1354 (Fed. Cir. 2001) and *Interactive Pictures Corp. v. Infinite Pictures, Inc.*, 274 F.3d 1371 (Fed. Cir. 2001).

It is to be understood that Applicant does not acquiesce to Examiner's characterization of the asserted art or Applicant's claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to Applicant's claimed subject matter. Moreover, Applicant does not acquiesce to any explicit or implicit statements or conclusions by the Examiner concerning what would have been obvious to one of ordinary skill in the art, obvious design choices, alternative equivalent arrangements, common knowledge at the time of Applicant's invention, officially noticed facts, and the like. Applicant respectfully submits that a detailed discussion of each of the Examiner's rejections beyond that provided above is not necessary, in view of the clear absence of teaching and suggestion of various features recited in Applicant's pending claims and lack of motivation to combine reference teachings. Applicant, however, reserves the right to address in detail the Examiner's characterizations, conclusions, and rejections in future prosecution.

Authorization is given to charge Deposit Account No. 50-3581 (GUID.048US01) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the undersigned attorney of record invites the Examiner to contact him at to discuss any issues related to this case.

Respectfully submitted,
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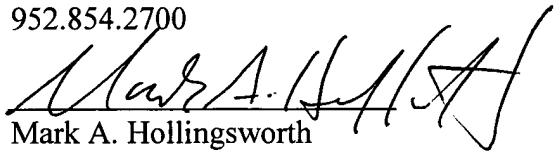
By: 
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